K110443

Section 5 - 510(k) SUMMARY

JUL 19 2011

SUMMARY OF SAFETY AND EFFECTIVENESS FOR BD Insyte™ Autoguard™ BC

1. **Submitted by:**
   Becton Dickinson Infusion Therapy Systems Inc.
   9450 South State Street
   Sandy, UT 84092

   Contact Information:
   Rand Pugmire
   Manager, Regulatory Affairs
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   Date Summary Prepared: February 11, 2011

2. **Device Name:**

Trade Name:	BD Insyte™ Autoguard™ BC
Common Name:	Peripheral Intravascular Catheter or IV Catheter
Classification:	80 FOZ - Intravascular Catheter
CFR Reference:	21CFR 880.5200 – Class II
Classification Panel:	General Hospital

3. **Predicate Devices:**
   Substantial equivalence is being claimed to the following legally marketed devices:

Trade Name:	BD Insyte™ Autoguard™
Common Name:	Intravascular Catheter
Classification:	80 FOZ - Intravascular Catheter
CFR Reference:	21CFR 880.5200 – Class II
Classification Panel:	General Hospital
Premarket Notification:	K013800

Trade Name:	SUPERCATH 5
Common Name:	Intravascular Catheter
Classification:	80 FOZ - Intravascular Catheter
CFR Reference:	21CFR 880.5200 – Class II
Classification Panel:	General Hospital
Premarket Notification:	K093546

4. **Product Description:**

   The purpose of the premarket notification is to introduce a new intravascular catheter, the BD Insyte™ Autoguard™ BC Shielded IV Catheter. This new catheter is identical to the BD Insyte™ Autoguard device (K013800) with the addition of a septum and actuator (blood control features) integrated into the catheter hub.

   The BD Insyte Autoguard BC catheter's, catheter hub has a built in blood control septum. The blood control feature is a single-use septum that automatically activates

to stop the blood flow in the catheter hub when the needle is removed from the catheter during initial insertion by the clinician. Blood flow from the catheter hub will be restricted immediately after the needle retraction until a secure luer connection is made. The flow path is permanently opened once a secure luer connection has been made.

BD Insyte™ Autoguard™ BC device is an over-the-needle, peripheral intravascular catheter that incorporates a spring-activated needle-shielding technology. Each catheter needle-shielding component includes a cylindrical needle-shielding barrel, a spring, a needle hub with flash chamber, and a needle.

The catheter component that is advanced into the vasculature is a BD Vialon™ polyurethane material. The catheter hub accommodates a luer slip or luer lock connection. It is available either with a straight or a winged catheter hub.

The BD Insyte Autoguard BC catheter needle-shielding technology provided the clinician with a user-activated button, the clinician pushes it to initiate the needle's retraction into the needle-shielding barrel. Once the button has been pushed and the needle retracted, the user cannot override the shielding mechanism to re-expose the needle tip.

The BD Insyte Autoguard BC catheter's needle incorporates BD Instaflash™ Needle Technology; this feature allows the clinician to visualize flashback through a notch in the side of the needle indicating that there is confirmation of vessel entry. This is available on the 20, 22, 24 gauge catheters only.

The BD Insyte Autoguard BC catheter is available in 16GA, 18GA, 20GA, 22GA, and 24GA sizes.

5. Indications for Use:

The BD Insyte™ Autoguard™ BC catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids.

6. Statement of substantial equivalence:

The characteristic of the BD Insyte Autoguard BC catheter are similar to those of the predicate devices. The similarities are:

Factor/Component	BD Insyte Autoguard BC	BD Insyte Autoguard (K013800)	SUPERCATH 5 (K093546)
Same Intended use	Yes	Yes	Yes
Same type of catheter material (Polyurethane)	Yes	Yes	Yes
Radiopaque catheter	Yes	Yes	Yes
Flashback visualization	Yes	Yes	Yes
Needle-shielding prevention feature	Yes	Yes	Yes
Ethylene Oxide sterilization	Yes	Yes	Yes
Single Use, sterile device	Yes	Yes	Yes
Multiple gauge sizes and needle lengths	Yes	Yes	Yes
Side-notch needle (certain gauges)	Yes	Yes	Yes

Blood Control feature - Septum	Yes	No	Yes

The BD Insyte Autoguard BC catheter has the same intended use and similar technological characteristics and the BD Insyte Autoguard (K013800) and the SUPERCATH 5 (K093546). Similar components and materials are used in both the BD Insyte Autoguard (predicate) and the BD Insyte Autoguard BC catheter.

Verification and validation activities were designed and performed to demonstrate that the BD Insyte Autoguard BC catheter met predetermined product specifications. See Section, 9, 18, 19, & 20.

7. **Risk Analysis:**
The BD Insyte Autoguard BC catheter was evaluated in accordance with ISO 14971:2009. No new types of safety or efficacy questions were identified for the BD Insyte Autoguard BC device. See Section 21.

8. **Bench Testing:**
Bench testing were performed to ensure the safety and effectiveness of the BD Insyte Autoguard BC catheter, to verify conformity to the standards listed in this application and demonstrate substantial equivalence to the predicates devices used in this application. No new issues of safety and effectiveness were raised with the testing performed, so therefore, the BD Insyte Autoguard BC is substantially equivalent. See Section 18.

9. **Clinical Use:**
A prospective, randomized, unblinded healthy volunteer (subjects) clinical study was conducted by BD to validate the design of the BD Insyte Autoguard BC catheter with the primary objective to evaluate the overall clinical acceptability of the new blood control feature, the clinician's perception of blood exposure during the IV Catheter insertion process, and the frequency of blood leakage observed from the IV Catheter hub. See section 20.

10. **Conclusions:**
Conclusions drawn from performance testing and clinical testing were conducted in accordance with consensus standards and design control requirements. Test results and technological characteristics of like gauge size catheters were shown to be equivalent between the subject device and the predicates. The differences among the devices do not raise any issues of safety or effectiveness. The subject BD Insyte Autoguard BC catheter met the minimum requirements and is substantially equivalent in design, materials, sterilization, principles of operations and intended use to the predicate.

Based on the above summary and the enclosed sections of this premarket notification regarding substantial equivalence to the predicate devices, Becton Dickinson Infusion Therapy Systems Inc. concludes that the BD Insyte Autoguard BC catheter is substantially equivalent to the BD Insyte Autoguard device, (K013800), and the SUPERCATH 5 device, (K093546) and does not raise any new questions regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Becton Dickinson Infusion Therapy Systems, Incorporated
Mr. Rand Pugmire
Managers Regulatory Affairs
Becton Dickinson & Company
9450 South State Street
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JUL 19 2011

Re: K110443
Trade/Device Name: BD Insyte™ Autoguard BC™ IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: July 7, 2011
Received: July 8, 2011

Dear Mr. Pugmire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
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Enclosure

Indications for Use

510(k) Number (if known): Unknown

Device Name: BD Insyte™ Autoguard BC™ IV Catheter

Indications for Use:

The BD Insyte™ Autoguard™ BC catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 7/18/4

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110443